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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,890	07/24/2006	Didier Courtois	112701-727	8593

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EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
07/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/595,890	COURTOIS ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received and entered on March 13, 2008. All evidence and arguments have been fully considered. Claim 5 has been cancelled. Claims 1-4 and 6-11 are pending and examined on the merits in this office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "large scale-up" in claims 1, 8 and 9 is a relative term which renders the claims and their dependents indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, "large scale-up" could mean the compatibility with a 1 L culture, a 100 L culture or a 100,000 L culture.

4. In claim 2, it is also unclear how applicant intends for the wave induction mechanism to "move from 8 to 20% of the surface area of the lower part of the culture chamber". For example, the mechanism could move from supporting 8% of the surface area to supporting 20% of the surface area, it could be actively involved in moving only

8-20% of the surface area, or only 8-20% of the surface area could be moved by the mechanism.

Claim Rejections - 35 USC § 101

5. The rejections under 35 U.S.C. 101 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4 and 6-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Singh (US 6,190,913). Claim 1 recites a cell culture apparatus comprising a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale-up. Claim 2 recites the cell culture apparatus according to claim 1, wherein the wave induction system moves from 8 to 20% of the surface area of the lower part of the culture chamber. Claim 3 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism moves part of the lower part of the culture chamber to an angle of

1 to 90 degrees. Claim 4 recites the cell culture apparatus according to claim 1, wherein the culture chamber comprises means to circulate air. Claim 6 recites the cell culture apparatus according to claim 1, wherein the culture chamber is a flexible plastic bag. Claim 7 recites the cell culture apparatus according to claim 1, wherein the culture chamber is filled from 10 to 80%. Claim 8 recites a method for cultivating plant cells, animal cells, or microorganisms, the method comprising providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale-up; and cultivating plant cells, animal cells, or microorganisms in the cell culture apparatus. Claim 9 recites a method for producing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules comprising providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale-up; and growing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules in the cell culture apparatus. Claim 10 recites the cell culture apparatus according to claim 1 wherein the wave induction mechanism moves part of the lower part of the culture chamber to an angle of 1 to 25 degrees. Claim 11 recites the cell culture apparatus according to claim 1 wherein the culture chamber is filled from 20 to 40%.

8. Singh teaches a cell culture apparatus comprising a flexible cell culture chamber (such as a plastic bag) and a wave induction mechanism (abstract, fig. 1). Singh

teaches that the wave induction mechanism is a pivot point which alternately rocks each side of the cell culture chamber, i.e. 50% of the cell culture chamber is lifted alternately (col. 4, lines 7-17, fig. 1). The pivot point (i.e. wave induction mechanism) in the method of Singh does not occupy more than 20% of the surface area of the cell culture chamber in the embodiment shown in fig. 1. Singh teaches that the wave induction mechanism moves the cell culture chamber between one and fifteen degrees (col. 4, lines 18-21). Singh teaches that the liquid phase may comprise 10 to 80% of total bag volume; as is clear from the figures, Singh anticipates the bag volume to be approximately 20 to 40% (col. 4, lines 30-34, figs. 1-3). Singh teaches that the cell culture chamber comprises a means to circulate air (col. 4, lines 34-49). Singh teaches a method of cultivating plant, animal, insect or microbial cells (i.e. biomass cells) using the apparatus (abstract).

9. Therefore, Singh anticipates all of the limitations of the cited claims.

10. Claims 1-4 and 6-11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hubbard (US 2005/0063250 A1). The claims are discussed above.

11. Hubbard teaches a cell culture apparatus comprising a flexible culture chamber (i.e. a fermentor) and a wave induction mechanism (a bag that is capable of being selectively pressurized and deflated; abstract). Hubbard teaches that the wave induction mechanism may be located under a portion of the bag, and alternately lifts between 5 and 50% of the bag shown in fig. 4 (p. 2, par. 34, fig. 4, p. 3, par. 51). The bag shown in fig. 4 is lifted at an angle of between 1 and 90 degrees. Hubbard teaches that the culture chamber may be a flexible plastic bag and that the culture chamber

comprises a means to circulate air (p. 2, par. 30, p. 3, par. 45). Hubbard teaches that the bags may be filled from 20 to 80% of the bag volume (p. 2, par. 29). Hubbard teaches that the apparatus may be used in a method for producing biomass cells, such as microorganisms (p. 2, par. 29).

12. Therefore, Hubbard anticipates all of the limitations of the cited claims.

Response to Arguments

13. Applicant's arguments filed March 13, 2008 have been fully considered but they are not persuasive. Applicant argues that the claims are sufficiently definite. Applicant argues that the cited references do not anticipate the claimed invention because they are incompatible with large scale-up. Applicant argues that the teachings of the cited references do not provide the same advantages as the invention recited in the instant claims.

14. In response to applicant's argument that the claims are sufficiently definite, it is noted that it is unclear how applicant intends for the wave induction mechanism to "move from 8 to 20% of the surface area of the lower part of the culture chamber". For example, the mechanism could move from supporting 8% of the surface area to supporting 20% of the surface area, it could be actively involved in moving only 8-20% of the surface area, or only 8-20% of the surface area could be moved by the mechanism. Although applicant argues that one of ordinary skill in the art would understand that the language is intended to describe the apparatus exemplified in the specification, applicant is reminded that the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, applicant's argument has not been found to be persuasive.

15. In response to applicant's argument that the cited references do not anticipate the claimed invention because they are incompatible with large scale-up, it is noted that the term "large scale-up" is a relative term which renders the claims indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, "large scale-up" could mean the compatibility with a 1 L culture, a 100 L culture or a 100,000 L culture. Since the metes and bounds of the claims are unclear, and the teachings of the prior art could be found to encompass compatibility with "large scale-up", the references anticipate the claims of the instant application. Applicant's argument that the references do not anticipate the claims is therefore not found to be persuasive.

16. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the advantages cited by applicant, such as lower cost, the use of a small motorized arm and the ability for the apparatus to be placed on a floor surface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, applicant's argument that the references do not teach the claimed features is not persuasive.

17. Therefore, applicant's arguments have been fully considered, but they are not found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM